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RECORD OF ORAL HEARING

U.S. PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte DAVID FIKSTAD and DANYI QUAN

Appeal 2010-001150
Application 09/871,318
Technology Center 1600

Oral Hearing Held: March 15, 2011

Before DEMETRA J. MILLS, ERIC B. GRIMES,
and LORA M. GREEN, *Administrative Patent Judges.*

APPEARANCES:

ON BEHALF OF THE APPELLANT:

MATTHEW L. FEDOWITZ, ESQUIRE
2020 K Street, N.W.
Washington, D.C. 20006

The above-entitled matter came on for hearing on Tuesday, March 15, 2011, commencing at 9:14 a.m., at the U.S. Patent and Trademark Office, 600 Dulany Street, Alexandria, Virginia, before Catherine Belka, a Notary Public.

PROCEEDINGS

THE USHER: Good morning. This is Mr. Matthew Fedowitz, Calendar Number 34, Appeal 2010-001150.

JUDGE MILLS: Good morning. Is it Mr. Fedowitz?

MR. FEDOWITZ: Yes, it is.

JUDGE MILLS: Okay, very good. Do you have a business card for the court reporter?

MR. FEDOWITZ: Yeah. Let me --

JUDGE MILLS: Okay. If not, you can provide her with the information afterward.

MR. FEDOWITZ: Yeah, let me get that. I think I left it my other briefcase actually.

JUDGE MILLS: Oh, okay.

MR. FEDOWITZ: Sorry about that.

JUDGE MILLS: Okay, we are familiar with the issues in your case, and you have 20 minutes and can begin when you're ready.

MR. FEDOWITZ: Okay. Well, Your Honors, thank you for taking time again to hear this case. As you're aware, this is the second time this case has been before the Board, however, unlike the first appeal, we've provided some new unrebutted evidence of nonobviousness of the currently claimed invention. Against this backdrop, therefore, I'd like to discuss two topics. Broadly speaking, these include the fact that the Examiner's contentions do not properly consider the complexities and difficulties involved with the claimed formulation, and that the Examiner responded improperly to the *Coop* declaration on procedural grounds by failing to perform a new analysis in view of the evidence demonstrating obviousness.

With regard to the technical complexities, the principal obstacle prohibiting the combination of the 925, 817, and 232 Patents is that they relate to different formulations containing pharmaceuticals having very different chemical properties. The only common thread between these patents is their discussion of their anti-estrogenic properties. Specifically, the Examiner relied on the 232 Patent for its disclosure of Lasofoxifene. The 232 Patent, however, does not disclose a transdermal form of Lasofoxifene that would be obvious to use in the claims under appeal. The reason for this is that the disclosure relied on by the Examiner is one for topical administration that consists of an aqueous or parenteral solution. As such, it does not provide any predictable way of determining how Lasofoxifene would interact with the polymer layer, the enhancer, the drug reservoir, the matrix, or any of the other excipients in the currently claimed transdermal delivery systems.

To support this position, we submitted the 132 Declaration from Dr. Coop. As you're aware, Dr. Coop has significant experience in the areas of medicinal chemistry and formulation design. In his declaration, Dr. Coop describe how the structural makeup and functional groups of a drug dictate how it may be formulated. For example, in paragraph 9 of Dr. Coop's declaration, he described how Lasofoxifene is very different structurally from all of the other drugs asserted by the Examiner to be similar to it. Then in paragraph 10, he described how the functional groups on each of these compounds affect their stability of their -- of the active ingredient alone and in combination with other excipients, as well as many other variables that must be considered in formulating a transdermal delivery system, as the one claimed. Each of these considerations add layers of unpredictability that

must be accounted for in formulating a transdermal delivery system, however, none of these physical or chemical properties were ever addressed by the Examiner. As a result, several assumptions must be made based on unpredictable components to conclude that an aqueous solution of Lasofoxifene, as in the 232 Patent, could be successfully and predictably used in the claimed transdermal drug delivery system.

With regard to the Examiner's assertions that individual drugs from a pharmacologic class would render the use of another drug from the same class obvious, we disagree, and we think the case law supports this. For example, the case law is clear that compounds with a similar structure are presumed to have similar properties. However, there is nothing with regard to compounds having a similar pharmacologic activity to say that they act similarly. In fact, the Federal Circuit has made it clear that just because a compound is found in a list of compounds, it does not mean those compounds are equivalent for all of their purposes. The Federal Circuit has also stated that when a chemical compound has sufficiently -- insufficiently similar structure, other compounds in that class are not prima facie obvious. That's the case here.

The Examiner rejected the pending claims on the assertion that when compounds have a similar pharmacologic activity, that activity is sufficient to render obvious the use of the compound in other formulations. With regard to the structural similarity between those compounds, the Examiner's statement that it would be obvious to use Lasofoxifene in the claimed device because it's an anti-estrogenic agent and functional equivalent of Lasofoxifene and -- or excuse me, Raloxifene and Tamoxifen is just not supported by the law. The Federal Circuit addressed functional equivalents

in this regard by stating expedients which are functionally equivalent to each other are not necessary obvious in view of one another. That's *Enray Scott*. With regard to the Examiner's statement that it would be obvious to try these different compounds in his Examiner's Answer, these different compounds -- - combination of compounds with regard to -- it would be obvious to try these different combinations. *KSR* specifically speaks to this as saying that. This is only the case when there are a finite group of -- finite number in this group.

Within the anti-estrogenic group, however, there are thousands of compounds. This can hardly be called a finite group. As a result, Lasofoxifene would not be obvious to try. This has become even more clear by taking into account the differences in chemical structure of the compounds cited by the Examiner. The commonalities between the compounds that the Examiner cited are not just present to make them interchangeable. For example, at MPEP 214408, this section provides direction for Examiners to conduct an analysis to determine obviousness based on chemical structure of the compounds involved. This analysis the Examiner skipped. For example, the first step of the analysis requires the consideration of structural similarity of the prior art. Only after structural similarity is found are the properties of these compounds considered. The Examiner, however, did not do this. In fact, throughout the record, the Examiner's own statements make it clear that he did not consider the structural similarity between Lasofoxifene and the other compounds that it considered interchangeable. This is particularly evident where the Examiner considered Lasofoxifene to be similar estradiol. As shown on page 15 of the

Appeal Brief, these compounds are shown to have vastly different structures and functional groups on them.

JUDGE GRIMES: The problem -- basic problem that I have with your chemical structural similarity argument is that the reference *Ebert* (ph.), the 925 Patent, lists a whole bunch of different chemical compounds and different classes of medical drugs that you could administer using this transdermal delivery device and your argument based on structural similarity could be presented with respect to any of the compounds in that list, and yet, *Ebert* tells us that a person skilled in the art could use this device to administer any of these drugs with routine experimentation. So given that these are all very structurally different drugs, why is the structural similarity of Lasofoxifene even really relevant to whether it could be used in this method – in this device

MR. FEDOWITZ: Because that's where the analysis starts. The analysis starts with this comparing the similarity between the compounds, okay? If the analysis started by saying this is the -- for instance, Lasofoxifene contains a heterocyclic nitrogen-containing ring and this compound contains a similar set of rings and a similar femicur (ph.) for structure, and starting with that chemical analysis of the structure and relating that the other compounds, that's the proper analysis. Then once you do that and then you can build out from that, that would -- that is how the analysis should proceed, however, that was not done here. All that was done was these compounds are part of this enormous group of anti-estradiol or estrogenic compounds, therefore, they're all related. But as -- you know, just looking at the structure of estradiol on page 15 of the Appeal Brief, you

can see that ring structure is vastly different than Lasofoxifene and the diversity of those --

JUDGE GRIMES: Now your analysis that you're positing here is based on the case law that determines whether a compound itself would have been obvious based on other known compounds of the art, correct?

MR. FEDOWITZ: That's correct.

JUDGE GRIMES: But you're not claiming to have invented Lasofoxifene?

MR. FEDOWITZ: No.

JUDGE GRIMES: Just this method --

MR. FEDOWITZ: Well, the -- that's correct. It's the transdermal delivery device using Lasofoxifene. So it's a combination. And we believe it's not obvious to use Lasofoxifene in this device just because the complexities involved with formulating a -- any drug delivery device has to take into account those chemical properties of the compound.

JUDGE GREEN: So you would say that *Ebert* is not enabling for the list of drugs that they have?

MR. FEDOWITZ: Pardon me?

JUDGE GREEN: *Ebert*, on column 4, says different types of drugs that could be used in the device are antiinflammatories, analgesics, antiarthritics, antispasmotics, antidepressants, antipsychotics, tranquilizers, antianxiety narcotic, antiparkinsonian, cholinergic, anticancer, et cetera, et cetera, et cetera. He seems to be saying that you can use a broad variety of different types of drugs for transdermal delivery, but you're saying each one of those would require an undue amount of experimentation to figure out how to use it in that particular device unless he specifically exemplified it?

MR. FEDOWITZ: Yeah, actually, I agree with that.

JUDGE GREEN: Okay.

MR. FEDOWITZ: Under 112, first paragraph I think, by him stating this broad -- these broad categories of compounds that could be used, he hasn't -- *Ebert* has not provided an enabling disclosure for all of those compounds. You know, there's an extent to which the four walls of that patent could read to say, you know, you could put all these compounds in there. Now, there'd be -- you ask any pharmaceutical formulation scientist to just grab any one of those, for instance, an anti-depressant that it lists here, it would be difficult for anyone to say, okay, I just put that into a device.

JUDGE GREEN: I'm not arguing that it wouldn't require some experimentation. Then the -- it becomes undue amount of experimentation and I don't know if that's been shown in this case or not. But I think what the analysis -- in this particular instance, you have to start with what the prior art teaches, and the prior art teaches, one, that you could put a broad variety of drugs in this and then you have a reference that your particular drug can be administered transdermally.

MR. FEDOWITZ: The reference that you -- the 232 Patent you're referring to states that -- first, it says Lasofoxifene in one place in the claims, then -- and I think it says, in four lines, it says for transdermal use, an aqueous solution similar to the parenteral solutions listed above can be used. Now, to put a drug into an aqueous solution, all that means is you have to take the crystalline structure, alter the pH of the solution to get it to go into solution. That's vastly different than getting -- having a drug in a matrix that's going to have to interact with various other excipients there to be able

to pass through the matrix, through a patient's skin. And not only that, only passing through the matrix, but to be able to formulate it so that it passes through the different layers of skin, along with the permeation enhancers and all those, the interactions between all of those chemicals in the formulation is much more difficult than the Examiner has set forth here. It's just -- to be able to say, look, there is an aqueous solution here that you could just pour on the skin and you can just combine that with a transdermal device that has, you know, several layers of complexity involved is just oversimplifying the process entirely, and that's what we tried to show with our declaration from Dr. Coop.

JUDGE GRIMES: The *Key* patent also says that the compounds of this invention could be administered individually or together in any conventional, oral, parenteral, or transdermal dosage form.

MR. FEDOWITZ: I think that also goes to Judge Green's statement about would *Key* be enabled under 112, first paragraph. I mean, that's a very broad statement.

JUDGE GRIMES: So your argument is that that's -- it's not enabling for that statement?

MR. FEDOWITZ: I'd have to go through and do an enablement analysis on this. But, you know, I think in *Key*, as long -- as well as *Ebert*, the inventors there have made some very broad statements. Of course, they're going to try to get the broadest coverage, but are they truly enabled under their patent to that wide set of what they're claiming?

JUDGE GRIMES: Isn't the Examiner entitled to presume that it's enabling for what it discloses?

MR. FEDOWITZ: To a certain extent. I mean, if they list -- let me put it this way. It's presumed to be enabled for the claims that are set forth in the patent, however, everything that's said in the specification of the patent is not encompassed by those claims.

JUDGE GREEN: But a patent -- you're allowed -- an Examiner is allowed to presume that a patent is enabled for all it discloses, and then the burden shifts to you to show that it's not enabled?

MR. FEDOWITZ: Right, within the scope of the claims of they're pursuing.

JUDGE GREEN: No, I don't think it's just within the scope of the claims, it's -- a patent is presumed to be enabled for all that it discloses during prosecution.

MR. FEDOWITZ: Yeah, I hear what you're saying. I think there is arguments being made to rebut something like that. For instance, if -- you know, on its face, the patent might list the broad groups of compounds that they are allegedly enabled for, but when the analysis really hits the fan and you're looking to see are those claims enabled for the vast group that the Applicant's applying for a patent for, there has to be analysis of whether those claims are enabled by the specification. Now, the claims in that patent are not as broad as the specification spells out. So, you know, I think, on one hand, the specification may say something and there is a finite group that claims in a patent are after and that's where the analysis lies.

JUDGE MILLS: Do we have any evidence of record that one of ordinary skill in the art in the transdermal art doesn't know how to make these modifications for particular functional groups on a chemical compound? I mean, I think it's a pretty mature art.

MR. FEDOWITZ: As far as one of ordinary skill in the transdermal arts, Dr. Coop is, you know, a formulation scientist, and from your previous opinion where you spoke to the predictability of compounds, we thought it best that Dr. Coop speak to the inability to interchange these compounds in a formulation such as a transdermal device. And so, he speak -- he describes what one of ordinary skill in the art is, then he describes how it would be difficult to interchange and be unpredictable and add all these levels of uncertainty to interchange these in a transdermal device. So he does speak to that.

JUDGE MILLS: Okay, do we have any other questions?

JUDGE GREEN: No.

JUDGE MILLS: No more questions.

MR. FEDOWITZ: Okay. Do I have a little more time or --

JUDGE MILLS: Sure

MR. FEDOWITZ: Okay.

JUDGE MILLS: Yeah, about 3½, 4 minutes.

MR. FEDOWITZ: Okay, good. With regard to just the procedural aspects here, if you take a look at the case *Enray Paseky* (ph.), the Examiner's procedure has been completely a contradiction to that case. Specifically, he issued a obviousness rejection which shifted the burden to the Applicant to rebut. We came back with a declaration from Dr. Coop, as well as our reply to the Office Action, which then shifted the burden back to the Examiner. The Examiner did not rebut that. All the Examiner did was restate the decision from the previous appeal. *Enray Paseky* specifically states that he has to rebut that either with his own evidence, which was not set forth, or provide some sort of explanation. Now, I think it's particularly

important to pay attention to that case because it deals exactly with this. Granted, in that case, it's -- the evidence dealt with secondary considerations, but we think it applies here as well. So on procedural grounds, we just feel that this was not dealt with correctly, so I just want to bring your attention to that case.

And, you know, finally, our thoughts are what we would like Your Honors to do is just overturn the Examiner's decision in this case based on the unpredictability in the art. The fact that we've presented unrebutted evidence to the complexities involved in combining these different pharmaceuticals, and that because the Examiner has made these overgeneralizations and really oversimplified the complexities involved with the formulation arts, that it just hasn't -- a prima facie case of obviousness just hasn't been set forth.

JUDGE MILLS: Okay, very good. We'll take your comments under advisement.

MR. FEDOWITZ: Thank you.

(Whereupon, the proceedings, at 9:33 a.m., were concluded.)